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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,142	06/26/2001	Hirobumi Aoki	Q64574	1209

7590 09/09/2004

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/869,142

**Applicant(s)**

AOKI ET AL.

**Examiner**

Christian L Fronda

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10, 11 and 60-72 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 12-58 and 62-71 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 is/are allowed.
- 6) ☒ Claim(s) 8, 10, 60, 61, 72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

1. Newly submitted claims 62-71 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of claims 62-71 and claims 8, 10, 11, 60, 61, and 72 are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of claims 8, 10, 11, 60, 61, and 72 can be made by another materially different process such as using recombinant molecular biology techniques for transforming a microorganism with a nitrilase and nitrile hydratase.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 62-71 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 8, 10, 11, 60, 61, and 72 are under consideration in this Office Action.

3. The rejection of claim 8 under 35 U.S.C. 102(a) as being anticipated by Kato et al. has been withdrawn in view of applicants' amendments and arguments filed June 6, 2004.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

4. Claims 8, 10, 60, 61, and 72 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed June 6, 2004 have been considered but are not persuasive. Applicants' position is that the specification provides adequate written description of the claimed mutant microorganism of the genus *Rhodococcus* and that the relevant characteristics are (1) a microorganism belonging to the genus *Rhodococcus*, (2) a property of converting a cyano group into a carboxyl group, and (3) a property of being defective or reduced in the activity of converting a cyano group into an amide group. The Examiner respectfully disagrees for reasons of record as supplemented below.

The claims are genus claims encompassing *Rhodococcus* microorganisms having any

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enzyme/protein of any amino acid sequence and structure which converts any cyano group on any molecule into any carboxyl group and having any enzyme/protein of any amino acid sequence and structure which is defective or reduced in activity of converting any cyano group on any molecule into any amide group. The scope of the claims includes many enzymes/proteins with widely differing structural, chemical, and physical characteristics, and the genus is highly variable because a significant number of structural differences between genus members is permitted.

Example 1 of the specification shows that treatment of *Rhodococcus* sp. ATCC39484 with NTG (N-methyl-N'-nitro-N-nitrosoguanidine) resulted in a strain SD826 which produced a large amount of 3-cyano benzoic acid, similar to the parent strain ATCC39484, and a greatly reduced amount of 3-cyanobenzamide and phthalic acid monoamide compared to parent strain ATCC39484. This does not provide a written description for the entire genus of *Rhodococcus* microorganisms having any enzyme/protein of any amino acid sequence and structure which is defective or reduced in activity of converting any cyano group on any molecule into any amide group since no specific enzyme attributed to this reduction in activity is identified, and no description of common structural and chemical properties of the encompassed enzymes/proteins which is defective or reduced in activity of converting any cyano group on any molecule into any amide group have been provided.

Furthermore, Examples 11-19 only provides a description of *Rhodococcus* microorganisms having an overexpression of nitrilase, nitrile hydratase, and amidase (SEQ ID NOs: 2, 4, 5, and 7) which is not representative of the entire genus of enzymes of any amino acid sequence and structure which converts any cyano group on any molecule into any carboxyl group because there is no description of common structural and chemical properties of nitrilase, nitrile hydratase, and amidase which is shared between genus members. Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Amending the claims to recite the specific encoding nucleotide sequence and amino acid sequence of the nitrilase, nitrile hydratase, and amidase (SEQ ID NOs: 2, 4, 5, and 7) may overcome the rejection.

### ***Conclusion***

5. Claim 11 is allowed.

6. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).


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Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571)272-0928. The official fax phone number (703)872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571)272-1600.

CLF

  
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